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4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1076]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0563. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice

OMB Control Number 0910-0563--Extension

Section 562 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360bbb-1) directs FDA to establish adequate dispute resolution (DR) procedures to ensure appropriate review of scientific controversies between FDA and members of regulated industry, including possible review by a scientific advisory committee. To implement this provision, we amended the general appeal regulation applicable across all FDA components (§ 10.75 (21 CFR 10.75)) to provide for advisory committee review (§ 10.75(b)(2)). At the same time and consistent with the mandates of section 562 of the FD&C Act, we adopted an approach whereby specific implementation procedures regarding scientific controversy associated with review of certain FDA decisions are detailed in center-issued guidance.

Accordingly, we developed the guidance for industry "Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice." We intend that the guidance inform manufacturers of veterinary and human drugs, including human biological drug products, on how to resolve disputes about scientific and technical issues relating to current good manufacturing practice (CGMP).

Disputes related to scientific and technical issues may arise during FDA inspections of pharmaceutical manufacturers to determine compliance with CGMP requirements or during FDA's assessment of corrective actions undertaken as a result of such inspections. The guidance recommends procedures that we believe encourage open and prompt discussion of disputes and lead to their resolution. The guidance describes procedures for raising such disputes to the Office of Regulatory Affairs, and Center levels and procedures for requesting review by the DR panel. The guidance is available on our website at https://www.fda.gov/regulatory-information/search-fda-guidance-documents, along with additional information regarding the resolution of scientific disputes at FDA.

We estimate only a nominal burden for the information collection and assume that one manufacturer will submit one request annually for tier-one DR and that it will take manufacturers approximately 30 hours to prepare and submit each tier-one DR request. Since our last request for OMB approval of the information collection, we have received no tier-two DRs.

In the *Federal Register* of December 9, 2020 (85 FR 79186), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Requests for tier-one DR	1	1	1	30	30

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated burden for the information collection reflects a decrease of 38 hours and a decrease of 1 request. This adjustment corresponds to a decrease in the number of submissions we have received over the last few years.

Dated: April 8, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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